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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,637	03/15/2002	Gerardo M. Castillo	PROTEO.P16CI	4148

74651 7590 12/28/2007

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EXAMINER	
WILLIAMS, LEONARD M	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
12/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/099,637	CASTILLO ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17 and 19-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17 and 19-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/11/2007 has been entered.

Response to Amendment/Arguments

The applicant's amendment received 10/11/2007 amending claims 17 and 25, and canceling claims 9-15. Claims 17 and 25 have been amended to delete the term amyloid from the claims.

The applicants argue on page 5 of the remarks that the examiner has perhaps mischaracterized the phrase "the therapeutic amount of the catechin selected for efficacy in treating amyloid (now deleted), alpha-synuclein or NAC fibrillogenesis in a mammalian subject" as being a part of the preamble. The examiner respectfully disagrees. As clearly described in the "Response to Arguments" section of the last office action (pages 2-3) the phrase stated above has been treated as an intended use statement in a composition claim and not solely as a part of the preamble.

The applicant's have argued that by removal of the term amyloid claims 17 and 19-29 opvercome the prior art of record. Specifically the applicant's argue that the prior art does not teach all the claim elements. The examiner respectfully disagrees.

As pointed out above the claims are drawn to pharmaceutical compositions with an intended use of treating alpha-synuclein or NAC fibrillogenesis. The intended use of a composition claim is generally accorded no patentable weight.

A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the ***intended use of a structure***, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

The examiner respectfully points out the following from MPEP § 2112.01: "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

All rejections of the last office action are maintained over claims 17 and 19-29, and are reproduced below.

Claims 17 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitsui (JP 10245342).

Mitsui discloses a pharmaceutical composition for diminishing the toxicity caused by □-amyloid protein comprising a catechin (or two or more catechins), such as epigallocatechin gallate and epicatechin gallate (see particularly page 1, 2nd paragraph, claims 1-3 at page 1., page 2 (0001), (0002)), and a pharmaceutical carrier (i.e., water). See also page 7 (0028), page 8 (0029).

In paragraphs 0027-0028 Mitsui discloses that tea polyphenol contains EGCg and ECg and that these can be extracted from tea leaves, separated and purified. Further the agent for use in the invention (catechin) can be used solely (anticipating claim 17) or mixed with auxiliary elements for regular use (anticipating claim 25). The agent can be administered by itself or with diluting agents or solvents such as water or alcohol or with diluents such as carboxymethyl cellulose.

In paragraph 0029, Mitsui discloses that the dosage of the agent can be determined based upon usage and even high dosages can be administered without worry of side effects as the compounds are highly safe.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19-24 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitsui as applied to claims 17 and 25 above, and further in view of Kuznicki.

Mitsui is as set forth above.

Mitsui does not teach administration of compounds in ranges from 10-100mg/kg or 10-1000mg/kg.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the dosages detailed by Kuznicki for Mitsui's agent as they are equivalent compounds, catechins are well tolerated with no significant side effects and Mitsui described that any tolerable effective dose is acceptable for treatment of β-

amyloid toxicity. Further the determination of an effective dosage of a compound is within the realm of routine experimentation for one of ordinary.

The examiner respectfully points out the following from MPEP 2144.05: "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." I*n re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969); Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed.Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 9-11 of the copending Application No. 10/762,444.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending Application is drawn to a drug product for treating amylodosis in a mammal comprising a composition a compound of Formula E which is epicatechin (see Fig. 1 B herein) and a pharmaceutically acceptable excipient. The claim of the instant application is drawn to a pharmaceutical composition for treating the same comprising (or consisting essentially of) epicatechin and pharmaceutically acceptable excipients in effective amounts within the copending Application claim.

Therefore, one of ordinary skill in the art would have found that the instant composition is clearly obvious in view of the copending Application No. 10/762,444.

Claims 25-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13'of the copending Application No. 10/610,349.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending Application is drawn to a pharmaceutical agent for treating amylodosis in a mammal comprising a composition a plant of the genus Uncaria which is known as green teas. The claim of the instant application is drawn to a pharmaceutical composition for treating the same comprising (or consisting essentially of) epicatechin present in green teas and pharmaceutically acceptable excipients in effective amounts within the copending Application. Therefore, one of ordinary skill in the ad would have found that the instant composition is clearly obvious in view of the copending Application No. 10/610,349.

Claims 25-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of the copending Application No. 10/610,346.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending Application is drawn to a pharmaceutical agent for treating amylodosis in a mammal comprising a composition a plant of the genus Uncaria which is known to green teas. The claim of the instant application is drawn to a pharmaceutical composition for treating the same comprising epicatechin present in green teas and pharmaceutically acceptable excipients in effective amounts within the copending Application claim. Therefore, one of ordinary skill in the art would have found

that the instant composition is clearly obvious in view of the copending Application No. 10/610,346.

Above obviousness-type double patenting rejections are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER